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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/800,531

03/15/2004

Samuel Achilefu

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01/07/2009

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/800,531	<b>Applicant(s)</b> ACHILEFU ET AL.	
	<b>Examiner</b> D. L. Jones	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 32-35 and 45-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-35 and 45-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 10/24/08 wherein claims 1-31 and 36-44 were canceled and claims 32-34 were amended. In addition, the Examiner acknowledges receipt of the declaration filed under 37 CFR 1.132 submitted 10/24/08.

**Note:** Claims 32-35 and 45-50 are pending.

## **RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS**

2. The Applicant's arguments and/or amendment filed 10/24/08 to the rejection of the claims made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed non-persuasive for the reasons set forth below.

**Notes:** It should be noted that the rejections have been somewhat modified to encompass all of the claims. In particular, it should be noted that the search has been expanded to encompass all of the biocompatible organic solvents of claim 35. The search was not further expanded because prior art was found which could be used to reject the claims when the organic solvent is cyclodextrin.

### **112 First Paragraph Rejection (Scope of Enablement)**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 32-35 and 45-50 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for cyanine dyes, does not reasonably

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provide enablement for all photodiagnostic and phototherapeutic dyes is MAINTAINED for reasons of record in the office action mailed 7/24/08 and those set forth below.

Applicant has provided a declaration supporting why the instant invention is not limited to any particular dye or groups of dyes. In particular, it is asserted that one of ordinary skill in the art would recognize that the invention reads on all fluorescent dyes known and it would not result in undue experimentation to determine which dyes may be used for a desired purpose.

Applicant's declaration was considered and found non-persuasive as enabling the claims for all possible dyes. In particular, it should be noted that the instant invention is directed to overcoming quenching/aggregation problems of cyanine dyes. Thus, as disclosed by the specification, the particular, cyanine dyes of interest were those of Formulae 1-4. also, page 22, lines 7-24 , and page 23, lines 1-2 (specifically, page 22, lines 8-9) disclose that it is known in the art that generally cyanine dyes form aggregates in aqueous media and that the addition of a biocompatible solvent of 1-50% restored the fluorescence and inhibited aggregation of the dye. Hence, Applicant is entitled to what is set forth and supported by the specification which is not that all dyes that are useful for photodiagnostic and phototherapeutic purposes may be used with the instant invention. Instead, the instant invention is enabled and support is provided for cyanine dyes. Hence, it would require an unnecessary burden to determine all other dyes, except cyanine dyes that aggregate/quench (to the extent of that of cyanine dyes) and wherein a biocompatible organic solvent concentration of 1-50% would be

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beneficial that are useful for administering to a subject for a desired purpose. Thus, the 112, first paragraph, rejection is deemed proper.

**112 Second Paragraph Rejections**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection claims 32-35 and 45-50 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is MAINTAINED for reasons of record in the office action mailed 7/24/08 and those set forth below.

Applicant asserts that the claims are not indefinite because the method requires that the dyes be administrable to a patient for photodiagnostic and phototherapeutic purposes and one would recognize that at least a threshold level of fluorescence is necessary.

Applicant's arguments are non-persuasive because while the claims are applicable to cyanine dyes, it is unclear what other dyes Applicant is intending to be compatible with the instant invention. Specifically, review of the specification discloses that Applicant recognized a problem with cyanine dyes and proposes that the problem of aggregation/fluorescence be corrected by combining the dye with a biocompatible organic solvent at a concentration of 1-50% of solvent. However, the claims are not limited to cyanine dyes. Hence, one cannot ascertain what other dyes Applicant is claiming that are compatible with the instant invention. Thus, the rejection is deemed proper.

**103 Rejection**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

I. The rejection over Licha et al in view of Song et al is WITHDRAWN. However, Licha et al may still be used to reject the claims as it relates to the biocompatible solvent, cyclodextrin. Thus, the rejection has been modified below.

II. Claims 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Licha et al (US Patent No. 6,083,485).

**Licha et al** disclose dyes which may be administered in vivo and radiates in the near infrared radiation region. The fluorescence dyes (e.g., cyanine dyes) may be used for various diagnostic purposes (see the entire document, especially, abstract; column 4, lines 6-28; columns 4-5, bridging paragraph; column 6, lines 17-45; columns 6-7, bridging paragraph). The compounds of Licha et al are water soluble, tolerable, and stable in vitro and in vivo (column 8, lines 31-37). The dye mixture may be administered by intravenous injection and they irradiated with light (column 8, lines 42-49). In addition, Licha et al disclose that for cyanine dyes, increased solubility in water and the presences of hydrophilic groups suppress the formation of aggregates and micelles (column 13, lines 15-22). The dye compositions may optionally contain common adjuvants, diluents, electrolytes, buffers, and substances such as cyclodextrin (column 14, lines 37-52). Thus, it would be obvious to a skilled artisan in the art to combine a cyanine dye with cyclodextrin and administer the compound to a subject because Licha et al disclose that cyclodextrin may be added to the dye. Also, the skilled artisan would

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recognize that the cyclodextrin is added to the dye prior to being administered to a subject because the prior art discloses that the dye compositions may contain various substances (i.e., such as cyclodextrin) and the compositions may be administered intravenously. In addition, a skilled artisan would be motivated to optimize the biocompatible solvent, cyclodextrin, such that the fluorescence of the mixture when administered to a subject is maximized and aggregation of the dye is minimized.

### **COMMENTS/NOTES**

3. It should be noted that the prior art cited above does not render all of the independent claims obvious because the specific solvents are neither obvious nor anticipated.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/  
Primary Examiner  
Art Unit 1618

January 5, 2009